

**Notice of Allowability**

Application No.

10/086,745

Examiner

Laura McGillem

Applicant(s)

DE JONG ET AL.

Art Unit

1636

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/13/2006.
2. ☒ The allowed claim(s) is/are 18-22 and 36-41.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
- ☒ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other \_\_\_\_\_

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### **EXAMINER'S AMENDMENT**

It is noted that claim 39 has been amended and claims 1-17 and 23-34 have been cancelled in the After Final amendment filed 03/13/2006.

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Stephanie Seidman on 3/22/2006.

The application has been amended as follows:

In the Claims:

Claim 35 has been cancelled.

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In claim 40, line 3, the phrase "a transformed cells" is grammatically incorrect and the word "cells" should be changed to --cell--.

In the Specification:

On page 1, in the Continuing Data, after " March 22, 2001", insert --now U.S. Patent No. 6,936,469--.

The use of the trademarks LIPOFECTIN, EFFECTENE, EU-FECTIN, GENEPORTER, FUGENE (paragraph 0090, for example) and SUPERFECT (paragraph 0226, for example) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

In paragraph 0090, "Lipofectin" should be changed to --LIPOFECTIN--.

In paragraph 0090, "Effectene" should be changed to --EFFECTENE--.

In paragraph 0090, "Eu-fectins" should be changed to --EU-FECTIN--.

In paragraph 0090, "GenePORTER" should be changed to --GENEPORTER--.

In paragraph 0090, "FuGENE 6" should be changed to --FUGENE 6--.

In paragraph 0226, "Superfect" should be changed to --SUPERFECT --.

The following is an examiner's statement of reasons for allowance: The instant claims are drawn to methods of monitoring the delivery of a large thymidine analog-labeled nucleic acid molecule into a cell and detecting the labeled nucleic acid molecule by flow cytometry, fluorimetry, cell imaging or fluorescence spectroscopy and determining the number of cells containing the label. A cationic compound can be used for a delivery agent. The claimed method is free of the prior art. The closest prior art is Nolan et al (WO00/34436, of record). Nolan et al teaches a method to employ fluorescence activated cell sorting to verify the delivery of at least one chromosome (1-10 megabases) into a host cell of interest including fibroblasts and parenchyma stem cells. Nolan et al also teach that the number of cells containing the label is determined following FACS analysis. However, Nolan et al does not specifically teaching fluorescently labeling the chromosome prior to delivering it into the cell.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Claims 18-22 and 36-41 (now claims 1-11) are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD  
3/27/2006

  
DAVID GUZO  
PRIMARY EXAMINER